IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

In re Entresto (Sacubitril/Valsartan) Patent Litigation)	C.A. No. 20-2930-RGA PUBLIC VERSION
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. HETERO USA INC., HETERO LABS LIMITED, HETERO LABS LIMITED UNIT III, MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	C.A. No. 19-2053-RGA PUBLIC VERSION
NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, GERBERA THERAPEUTICS, INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	C.A. No. 22-1395-RGA PUBLIC VERSION

DECLARATION OF DEFOREST MCDUFF, PH.D.

I, DeForest McDuff, declare as follows:

1. I am an economist and founder of Insight Economics, an economic consulting firm with a focus on business economics and intellectual property, among other areas. I have been engaged by the law firm Daignault Iyer LLP on behalf of MSN Pharmaceuticals, Inc. ("MSN") to provide expert testimony in this action. If called to testify at a hearing or trial, I could and would testify to the following information and opinions.

I. Introduction

A. Qualifications

2. I am an economist at Insight Economics with extensive experience in consulting, finance, education, and business. I provide economic expertise as a consultant and expert witness in many areas, including economic harm (lost profits, reasonable royalties, loss of value, loss of reputation, and others), intellectual property (patents, trademarks, trade secrets, copyright), antitrust (monopolization, price discrimination, tying, price fixing), competition (economic harm, market definition, unfair competition, false advertising), valuation, financial analysis, commercial success, irreparable harm, unjust enrichment, and other areas.

3. My experience includes more than 150 expert reports and declarations, 80 expert depositions, and 30 trials and hearings. My expert opinions have been relied upon by clients, courts, and government agencies. My consulting experience includes valuation analysis, regulatory analysis, licensing, negotiation, pricing, business strategy, product launches, and other topics. I founded Insight Economics in 2017.

4. I have significant experience evaluating the economics of the pharmaceuticals industry. I have provided expert analysis and consulting in over 75 cases involving pharmaceuticals and related products, including evaluations of economic damages, competition, commercial success, irreparable harm, and other issues. I have evaluated a number of pharmaceutical product launches in a litigation setting and an advisory role, and have published articles and taught continuing legal education on pharmaceutical topics as well. I have been recognized as a leading economic expert on patent cases by IAM Media.

5. I am an Assistant Teaching Professor in the Department of Economics at the University of North Carolina at Chapel Hill. I earned a Ph.D. in Economics from Princeton University, where I received a National Science Foundation Graduate Research Fellowship for my academic research in financial economics and applied microeconomics. I graduated summa cum laude with a B.A. in Economics and a B.S. in Mathematics from the University of Maryland. My curriculum vitae contains more details on my education, experience, and prior testimony and is provided as Exhibit A-1.

B. Scope of work

6. For this declaration, I was asked to review and respond to the declaration of Dr. Christopher Vellturo ("Vellturo Declaration") with respect to irreparable harm, balance of hardships, and public interest in support of Plaintiff's motions for a preliminary injunction against MSN.[1] This declaration summarizes my opinions and the bases for those opinions, which are subject to revision based upon additional information or analysis.[2]

II. Background

7. Novartis is a global pharmaceutical company with products and research in a variety of therapeutic areas.[3] Novartis employs more than 75,000 employees across the world and sells products in more than 130 countries, with company headquarters in Switzerland.[4] In 2023, Novartis earned annual revenues of $45.4 billion and net income of $8.6 billion.[5]

8. Entresto is a branded product sold by Novartis that treats heart failure and hypertension.[6] As of 2023, Novartis reports that Entresto has reached more than 2 million patients

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[1] Vellturo Declaration, 8/2/2024.
Opening Brief in support of Novartis's Motion for a Rule 62(d) Injunction Pending Appeal and Temporary Restraining Order Pending Resolution of this Motion, 8/2/2024.
Opening Brief in Support of Novartis's Motion for Preliminary Injunction Against MSN, 8/2/2024.

[2] Insight Economics is being compensated at a rate of $950 per hour for my work and at lower rates for time spent by others on my team. The compensation of Insight Economics does not depend on the substance of my testimony or the outcome of this matter. I have evaluated the motion by Plaintiff and corresponding declarations submitted for just a short time period and thus reserve the right to continue developing my opinions based upon new information and/or analysis.

[3] Novartis, Annual Report, 2023, at 21.

[4] Novartis, Annual Report, 2023, at 21.

[5] Novartis, Annual Report, 2023, at 21, 43.

[6] Novartis, Annual Report, 2023, at II.

in the United States and earned $6.0 billion annually worldwide.[7]

9. U.S. Patent No. 8,101,659 ("the '659 patent") issued on January 24, 2012, and claims certain pharmaceutical compositions, stated to treat certain hypertension and heart failure conditions, among others.[8] U.S. Patent No. 11,096,918 ("the '918 patent") issued on August 24, 2021, and claims an amorphous solid form of certain compounds, stated to be "useful for the treatment of hypertension and/or heart failure."[9]

III. Analysis

A. Irreparable Harm

10. I understand that irreparable harm is one factor considered by courts in evaluating whether injunctive relief is appropriate in these circumstances.[10] I understand that when a patentee's harm is quantifiable and compensable, the patentee has not suffered irreparable harm.[11]

11. The Vellturo Declaration claims that Novartis will suffer irreparable harm absent an injunction based upon the following: (1) direct impact via loss of sales and market share,[12] (2) potential price erosion,[13] (3) difficulty in forecasting "but-for revenues",[14] (4) MSN's inability to pay a potential judgment,[15] (5) harm to Entresto following generic withdrawal from a possible "accelerated reduction" in education and support efforts,[16] and (6) harm to other product lines separate from Entresto.[17]

12. In my opinion, the potential harms described by the Vellturo Report are overstated and, to the extent they occur, can be compensated through monetary remedy. In contrast, the potential harm to Novartis will not be irreparable, for the following reasons.

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7 Novartis, Annual Report, 2023, at II, 44.
8 U.S. Patent No. 8,101,659 B2, 1/24/2012, "Methods of Treatment and Pharmaceutical Composition."
9 U.S. Patent No. 11,096,918 B2, 8/24/2021, "Amorphous Solid Form of Compounds…"
10 *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).
Apple, Inc. v. Samsung Elecs. Co., 695 F.3d 1370 (Fed. Cir. 2012).
Altana Pharma AG and Wyeth v. Teva Pharmaceuticals USA, Inc., 566 F.3d 999 (Fed. Cir. 2009).
11 *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).
12 Vellturo Declaration, 8/2/2024, ¶¶ 47-50.
13 Vellturo Declaration, 8/2/2024, ¶¶ 51-56.
14 Vellturo Declaration, 8/2/2024, ¶¶ 58-62.
15 Vellturo Declaration, 8/2/2024, ¶¶ 63-67.
16 Vellturo Declaration, 8/2/2024, ¶¶ 68-74.
17 Vellturo Declaration, 8/2/2024, ¶¶ 75-77.

13. *First*, any loss to Novartis can be compensated via monetary remedy using standard approaches to calculating damages. The Vellturo Declaration argues that MSN's product will cause losses of sales, market share, and/or price erosion. However, all of these alleged losses are standard economic analyses that can be quantified and compensated. Some degree of uncertainty and resulting estimation is inherent in almost every damages analysis, but that does not make the underlying harm irreparable.

14. Standard damages remedies can be used to compensate Novartis if there is harm caused by MSN's alleged infringement. Lost profits (if applicable) are commonly calculated based on the *Panduit* factors, which consider demand for the patented product, availability of non-infringing alternatives, capacity to make lost sales, and the ability to quantify damages.[18] A reasonable royalty (if applicable) is commonly calculated based on the determination of a hypothetical negotiation between licensor and licensee per the *Georgia-Pacific* factors.[19] Each of these factors can be determined in ordinary discovery, and these forms of economic damages are frequently evaluated and quantified by economists in patent infringement matters involving pharmaceuticals and other products. Even in this matter, the Vellturo Declaration calculates potential harm in the form of lost revenues and profits, supporting the conclusion that any harm in this matter is quantifiable and therefore compensable by remedies at law.[20]

15. Market entry by generic competitors is standard practice in the pharmaceutical industry. While the timing may be uncertain, eventual generic entry is likely and inevitable for every product. Indeed, Novartis has acknowledged the potential of generic entry and corresponding litigation in its Annual Reports: "In the US, Novartis is in ANDA litigation with generic manufacturers… Any US commercial launch of a generic Entresto product prior to the final outcome of Novartis combination patent appeal, or ongoing litigations involving other patents, may be at risk of later litigation developments."[21]

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18 *Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152, 1156 (Fed. Cir. 1978).
Rite-Hite Corp. et al. v. Kelly Company, Inc., 56 F.3d 1538, 1545 (Fed. Cir. 1995).

19 See, for example, *AstraZeneca AB et al. v. Apotex Corp.*, F.3d 1324, 1330 (Fed. Cir. 2015).

20 Vellturo Declaration, 8/2/2024, Exhibit 14.

21 Novartis, Annual Report, 2023, at 47.

16. The Vellturo Declaration indicates that Novartis may elect a competitive response "along a spectrum", [redacted].[22] Either way, the result is the same, since the loss in the form of market share loss or price erosion loss can both be quantified.

17. The Vellturo Declaration indicates that potential price erosion [redacted] would be "difficult or impossible to fully reverse" if generic competition later withdrew.[23] However, the Vellturo Declaration acknowledges that "there is considerable variation in observed outcomes in generic entry scenarios."[24] In my experience, branded products often maintain prices or even raise prices when generic competition occurs (due to market segmentation between brand and generic),[25] and so price erosion is not likely to occur [redacted]. Further, prices in a competitive market can adjust to competition, just as they can adjust to a lack of competition should an injunction later be granted. The claims by the Vellturo report that prices would be "difficult or impossible" to reverse are unsupported and unfounded.

18. *Second*, the Vellturo Declaration's claims regarding "difficulty in forecasting 'but-for' revenues"[26] are overstated and contrary to the underlying data. While there may always be some degree of uncertainty associated with calculating economic damages, there do not appear to be any factors that make the calculation particularly difficult in this case. Indeed, the figure put forth by the Vellturo Declaration (and reproduced below) on the "difficulty" of forecasting sales is unpersuasive, since the actual amounts sold by Novartis appear to track the forecasts within a reasonable margin of error.[27] Year-on-year percentage growth of Entresto net sales in the U.S. has

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22 Vellturo Declaration, 8/2/2024, ¶ 51.
23 Vellturo Declaration, 8/2/2024, ¶ 51.
24 Vellturo Declaration, 8/2/2024, ¶ 50.
25 Yu, Gupta (2014), "Pioneering advantage in generic drug competition," International Journal of Pharmaceutical and Healthcare Marketing, Vol. 8 No. 2, 2014, at p. 127. ("Typically, after losing patent exclusivity, the brand drug maintains its price at the pre-expiration level, or even raises prices slightly, as generic competitors enter the market at substantially lower prices and rapidly drop prices with the entry of more competitors.")
Regan, Tracy L. (2008), "Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market," International Journal of Industrial Organization 26:930–948, at 947.
26 Vellturo Declaration, 8/2/2024, ¶¶ 58-62.
27 Vellturo Declaration, 8/2/2024, Figure 2.

also remained relatively constant over the last four years and is expected to decline in 2024, per the Vellturo Declaration's own calculations, which suggests future growth that is unlikely to deviate substantially from historical trends on the high side.[28]

Vellturo Declaration, Figure 2

19. Further, any damages analysis will be conducted using actual data with hindsight, based on both the actual sales data shown in the figure above and more market data available from both Novartis, MSN, and any other generics that have come to market. Thus, rather than forecasting the unknown size of a future market, an evaluation assessing competition after the fact will assess the actual market with actual data. In my opinion, there are no factors here that make a damages determination particularly unusual or difficult.

20. *Third*, the Vellturo Declaration does not appear to allege any sort of reputational harm or operational difficulty faced by Novartis as a result of MSN's entry, and nor should it. Novartis is one of the largest pharmaceutical companies in the world, with more than $40 billion

[28] Exhibit B-1.
Vellturo Declaration, 8/2/2024, Exhibit 13.
The annual growth rate of Entresto net sales in the U.S. has declined from 38% in 2020 to 30% in 2023, with a further decline to 26% projected for 2024.

in annual worldwide revenues, nearly $10 billion in annual operating profit, $100 billion in total assets, and $13 billion in cash and cash equivalents. See Exhibits B-2 and B-3. Economic harm from infringement may occur and may be calculated at some point, but harm from just one product will not fundamentally change Novartis's standing, finances, or operations.

21. *Fourth*, I understand that MSN has sufficient financial resources to pay for any potential harm caused by its infringement, if any. I understand that Bharat Reddy Chintapally, an Executive Director of MSN Laboratories, has provided estimated figures on its potential MSN launch and MSN's financial ability to satisfy a judgment. According to Mr. Chintapally, [redacted] MSN through December 2024.[29] I understand that MSN intends to escrow its revenue and profits until the resolution of any appeals, should an award to Novartis be needed.[30]

22. More broadly, [redacted] to draw from to satisfy any judgment.[31] I understand that MSN estimates each of those figures to be greater in 2025.[32]

23. As the Vellturo Declaration acknowledges, a large portion of MSN's ability to pay a damages claim will come from the revenues and profits that it earns on the market. As long as MSN does not price too low compared to Novartis, it should earn a significant fraction of any harm it may later owe. For example, if MSN prices at 80% of the brand with a 90% generic margin, compared to Novartis pricing at 100% with a 80% brand margin, MSN would earn $0.72 per dollar (= $1.00 × 80% × 90%) for each $0.80 per dollar lost by Novartis (= $1 × 80%), even assuming a one-to-one loss (which may or may not be applicable, depending on the market dynamics). Thus, even if a damages claim were in the hundreds of millions of dollars as alleged by the Vellturo Declaration, MSN would likely earn at least a significant fraction of the loss by being on the market

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29 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶¶ 8-9.
30 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶ 10.
31 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶¶ 3, 11.
32 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶ 3. MSN also has very substantial fixed assets, which could be used to support any necessary borrowing.

and, combined with its company financials overall, including the ability to access capital markets as necessary, should likely be able to afford such a payment while otherwise maintaining its operations.[33] Under the assumptions of the Vellturo Declaration, by entering the market, MSN would be taking an economically irrational risk of putting itself out of business. Such an assumption is unfounded, as I understand MSN has extensive experience planning for and conducting at-risk launches.[34]

24. Further, the projections in the Vellturo Declaration of the extent of likely harm are very likely overstated. The Vellturo Declaration projects revenue loss of [redacted] for multiple generics and [redacted] revenue loss for a single generic after just 4 months.[35] These scenarios appear to be overstated and driven by [redacted]. More likely, the amount of loss would be limited primarily to market share loss.

25. The Vellturo Declaration's notion that MSN would cause a "jailbreak scenario" of multiple generic competitors, as the Vellturo Declaration describes it,[36] unfairly places blame on MSN for actions taken (or not taken) by other competing generics, and thus improperly inflates Novartis' alleged harm. Whatever actions are taken and/or potential economic impact is caused by other competitors can be considered and compensated in a similar manner by those other competing companies. Indeed, the Vellturo Declaration improperly [redacted] it calculates MSN alone would make in the "Multiple Generic Entry" scenario to the [redacted].[37] A reliable comparison would need to apportion the alleged harm among the assumed multiple generic entrants before comparing it to MSN's expected incremental profits.

26. Ultimately, the Vellturo Declaration opines that Novartis may lose several hundred million dollars out of billions earned annually.[38] While that may represent a relatively large damages claim in some contexts, the harm, should it occur, would not cause any adverse impact

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33 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶¶ 6-11.
34 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶ 5.
35 Vellturo Declaration, 8/2/2024, Exhibit 14.
36 Vellturo Declaration, 8/2/2024, ¶ 12.
37 Vellturo Declaration, 8/2/2024, ¶¶ 66-67, Exhibit 13.
38 Vellturo Declaration, 8/2/2024, ¶ 65.

on Novartis as a company. The amounts at stake merely represent alleged damages that can be and should be compensated through the ordinary process.

27. While MSN has the financial resources for any potential harm caused by its infringement, I also understand that MSN has the potential to acquire insurance coverage for any excess loss.[39] I understand that under the scenario that MSN acquires the proper litigation risk coverage, any damages would not affect MSN's cash reserves, but would be covered by the policy.

28. *Fifth*, the Vellturo Declaration's claims about harm to Entresto and non-compensable harms to "other product lines"[40] are speculative and unsupported by economics. The Vellturo Declaration argues that Novartis "may accelerate its planned reduction of its physician education / promotional efforts and patient support programs."[41] First, I note that the Vellturo Declaration makes no attempt to quantify the extent to which generic entry "may accelerate" Novartis' course of action beyond what is already "planned." Second, as an economic matter, there is no basis to think, and the Vellturo Declaration does not offer any, that the claimed revenue loss from generic entry will actually cause such an unspecified acceleration. With more than 5,000 full-time scientists, physicians, and business professionals,[42] and more than $11.3 billion in annual research and development expenditures,[43] Novartis will continue to put capital and funding towards profitable sales and marketing efforts, as needed and desired. Finally, the Vellturo Declaration's assertion that the same employees also promote other Novartis products,[44] thus generating additional revenue from those products, makes the simultaneous claim that Novartis would reduce their activities less credible from an economic standpoint.

29. Even if Novartis may choose to re-allocate its sales and marketing resources after generic entry by MSN and others, there is nothing irreparable about this. With more than $50 billion in annual sales across dozens of products, Novartis can certainly find alternative uses for

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39 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶ 13.
40 Vellturo Declaration, 8/2/2024, ¶¶ 68-77.
41 Vellturo Declaration, 8/2/2024, ¶ ¶ 11, 70.
42 Novartis, Annual Report, 2023, at 30.
43 Novartis, Annual Report, 2023, at 43.
44 Vellturo Declaration, 8/2/2024, ¶74.

those resources and sales staff, if it chooses to do so.[45] The Vellturo Declaration's assertions of a loss of "flexibility" regarding personnel decisions, and "likely" related costs,[46] are speculative. There are not constraints or particular issues with re-allocating resources that I have seen that fundamentally causes competition to create irreparable harm for Novartis.

30. On balance, based on my own review and assessment, Novartis is not likely to suffer any irreparable harm from competition that cannot be compensated via monetary remedy.

B. Balance of Hardships

31. I understand that the balance of hardships is another factor considered by courts in evaluating whether injunctive relief is appropriate.[47]

32. The Vellturo Declaration argues that the balance of hardships favors granting a preliminary injunction based on Novartis's lost profits being purportedly greater than MSN's gained profits on a dollar-for-unit basis (*i.e.*, a branded drug product typically sells for greater than a generic drug product and so the dollars lost by the brand are greater than the dollars gained by the generic).[48] However, this argument is simply a reiteration of the Vellturo Declaration's position on compensability. The fact that Novartis's brand product might have earned more but for infringement as compared to a generic at a lower price does not cause a particular hardship as long as Novartis is able to be fairly compensated for any such infringement (which it would be, as described above). Such an argument would unreasonably yield a balance of hardship in favor of a branded product in every case.

33. To the extent that Novartis has reached agreements that allow other competitors to come on the market,[49] that competition would be outside the scope of any impact caused by MSN. Indeed, as a matter of both economics and equity, Novartis should be responsible for the results of that knowing and voluntary decision, which should not be part of the balance of hardships.

34. Further, the Vellturo Report omits the significant harm to MSN from not being able

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45 Novartis, Annual Report, 2023, at 46.
46 Vellturo Declaration, 8/2/2024, ¶ 76.
47 *See*, *e.g.*, *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).
48 Vellturo Declaration, 8/2/2024, ¶¶ 78-79.
49 Vellturo Declaration, 8/2/2024, ¶ 6.

to launch due to a preliminary injunction. Unlike Novartis, which has been selling Entresto for 9 years since 2015 and will inevitably face competition from generic suppliers at some point, MSN has a more limited window to earn a return on its investment.[50] Generic entrants frequently compete for position based on time to market,[51] and MSN may lose a significant first-mover advantage if it is not allowed on the market when it is ready to launch. A preliminary injunction will allow other generic competitors to better prepare to compete with MSN and may erode MSN's market opportunity. Accordingly, as compared of the overall opportunity, MSN has more to lose from not being able to come to market than Novartis has to gain by keeping MSN off the market. Then, after accounting for any compensation Novartis may seek, the primary loss associated with an injunction would be to MSN.

35. On balance, based on my own review and assessment, the balance of hardships weighs somewhat against a preliminary injunction.

C. Public Interest

36. I understand that the party requesting an injunction may also contend that the public interest would not be disserved by the issuance of an injunction.[52]

37. The Vellturo Declaration argues that the public interest favors granting a preliminary injunction based on: (1) the importance of patent protection, and (2) harm to individuals who may not be treated with Entresto due to lack of continuing education.[53] However, in my opinion, the Vellturo Declaration has not shown a strong public interest favoring a preliminary injunction.

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50 Declaration of Bharat Reddy Chintapally, 8/6/2024, ¶ 15.

51 Yu, Gupta (2014), "Pioneering advantage in generic drug competition," International Journal of Pharmaceutical and Healthcare Marketing, Vol. 8 No. 2, 2014, at p. 142. ("[O]n average, [first generic entrants] enjoy an 80 percent higher market share than the second generic entrant, and 225 percent higher market share than the third.")

FDA (2019), "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices," p. 1, 2, 9.

"We show that generic drug prices after initial generic entry decline with additional competition using both the average manufacturer prices (AMP) reported to the Centers for Medicare and Medicaid Services (CMS) and invoice-based wholesale prices reflecting pharmacy acquisitions from IQVIA's National Sales Perspective database (NSP)."

52 *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

53 Vellturo Declaration, 8/2/2024, ¶ 80.

38. On the first point, the Vellturo Declaration essentially provides a one-sided argument on the merits of patent protection. In fact, there is an economic balancing for the public interest between upholding patent rights versus the benefits to the public from competition.[54] The Vellturo Declaration does not seriously contend with this balancing. Given Entresto's 9 years of exclusivity on the market and more than $12 billion earned in the U.S. since launch in 2015 (see Exhibit B-1), a reasonable case can be made that Novartis has already been reasonably compensated for its investment in bringing a new product to market. Any additional compensation that Novartis should have earned due to patent exclusivity can be sorted out in the ordinary course.

39. Notably, Novartis appears to have already benefitted from a litigation stay enjoining FDA approval of MSN's ANDA products for nearly four years, based on the '659 patent, which was later held to be invalid. As Novartis notes, the '918 Patent is not eligible for a statutory stay. Additionally, Novartis continued to enjoy the benefits of exclusivity for another year after that, pending the FDA's recent approval decision. The public interest in competition should therefore be weighed more heavily in these circumstances.

40. On the second point, the Vellturo Declaration argues that Novartis's reduced investments would result in lesser physician awareness and lower patient use, all else equal. As discussed above, this claimed effect is dubious as an economic matter; neither Novartis' ability nor incentive to continue these investments would change materially with MSN's entry. Moreover, after 9 years of exclusivity and product awareness and support efforts resulting in $12 billion in U.S. revenue since launch (see Exhibit B-1), there has already been a very substantial amount of awareness and familiarity established in the market. But any decrease in future awareness, even if it exists, is likely to be far less than the public benefit of lower prices for patients and resulting increased demand that can result from generic competition.

41. On balance, based on my own review and assessment, the public interest does not

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[54] "[T]he touchstone of the public interest factor is whether an injunction, both in scope and effect, strikes a workable balance between protecting the patentee's rights and protecting the public from the injunction's adverse effects." *i4i Ltd. P'ship v. Microsoft Corp*., 598 F.3d 831, 863 (Fed. Cir. 2010); see *Hybritech Inc. v. Abbott Labs*., 849 F.2d 1446, 1458 (Fed. Cir. 1988) ("Typically, in a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief.").

appear to favor a preliminary injunction.

IV. Conclusion

42. In my opinion, based on the facts and information described herein, from an economic perspective: (1) any harm to Novartis caused by the entry of MSN's product while litigation is pending will not be irreparable (Section III.A), (2) the balance of hardships does not favor a preliminary injunction (Section III.B), and (3) the public interest does not favor a preliminary injunction (Section III.C).

43. I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct. Executed on August 6, 2024 in Chapel Hill, North Carolina.

DeForest McDuff, Ph.D.

Insight Economics

Exhibit A-1: McDuff CV

DeForest McDuff, Ph.D.

August 2024

DeForest McDuff, Ph.D. is a consultant and experienced expert witness in economics, business, damages, competition, and other areas. He provides economic analysis that is relied upon by clients, courts, and government agencies to support sound economic decisions. Dr. McDuff has been named as a nationally recognized economic expert in the IAM Patent 1000. He founded Insight Economics in 2017.

Dr. McDuff provides economic consulting and testimony in many areas, such as:

- Damages: lost profits, reasonable royalty, business impact, loss of value;
- Intellectual property: patents, trademarks, trade secrets, copyrights;
- Antitrust: market definition, restraints on competition, competitive impact;
- Competition: economic harm, unjust enrichment, false advertising;
- Economic analysis: irreparable harm, balance of hardships, class certification;
- Other areas: valuation, financial analysis, labor, employment, and more.

Dr. McDuff's experience includes more than 150 expert reports, 80 depositions, and 30 trials and evidentiary hearings in courts across the country. His experience outside the courtroom includes regulatory analysis, fair market valuation, licensing, negotiation, product launches, strategic analysis, and other topics. He regularly works in the pharmaceutical, medical device, electronic, and software industries, among others.

Dr. McDuff is a teaching professor in the Department of Economics at the University of North Carolina at Chapel Hill. He earned a Ph.D. in Economics from Princeton University, where he received a National Science Foundation Graduate Research Fellowship for his academic research in financial economics and applied microeconomics (awarded to 25 graduate students in economics nationwide each year). Dr. McDuff has published in peer-reviewed academic journals and widely review industry publications. He graduated summa cum laude with bachelor's degrees in economics and mathematics from the University of Maryland.

Dr. McDuff is also the co-founder of Integrity Seminars, a company dedicated to teaching academic integrity to college students since 2006. The company offers the Academic Integrity Seminar, a personalized online educational intervention administered to more than 100 colleges and universities nationwide to promote the importance of social trust and mutual obligation in academic, economic, and personal relationships.

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Professional Experience

Insight Economics (www.insighteconomics.com). San Diego, CA and Raleigh, NC. Partner, 2017 to present.

University of North Carolina at Chapel Hill. Chapel Hill, NC. Assistant Teaching Professor, Department of Economics, 2020 to present.

Integrity Seminars (www.integrityseminar.org, formerly Academic Integrity Seminar). Partner, 2006 to present.

Intensity (formerly Quant Economics). San Diego, CA and Boston, MA. Economist from 2009 to 2012, Senior Economist from 2012 to 2013, Vice President from 2013 to 2017, Head of Boston Office from 2015 to 2017.

JPMorgan Chase. New York NY. Trading Analyst, 2006 to 2007.

Princeton University. Princeton NJ. Economic Research Assistant, 2004 to 2006.

Education

Ph.D. in Economics, M.A. in Economics, Princeton University, 2009.

B.A. in Economics, B.S. in Mathematics, University of Maryland, College Park, summa cum laude, 2004.

Professional Memberships

American Economic Association (AEA).

Licensing Executives Society (LES).

Publications

DeForest McDuff, Gary Pavela, Gregory Pavela, and Justin Coen, "Driving Plato's Chariot: Lessons on Student Ethical Development," (2024) Amazon Publishing.

DeForest McDuff, Sophia Luo, and Mickey Ferri, "Thinking Economically About Nexus in Commercial Success," (2023) Landslide, Volume 15, Number 4.

DeForest McDuff, Mickey Ferri, and Brett Irvin, "Using Multiple Apportionment Methods in IP Damages," (2023), IAM Publication.

DeForest McDuff, Mickey Ferri, and Noah Brennan, "Patents and Antitrust in the Pharmaceuticals Industry," (2021) The Journal of the Antitrust and Unfair Competition Law Section of the California Lawyers Association 31(2): 127-155.

DeForest McDuff, Mickey Ferri, and Noah Brennan, "Thinking Economically About Blocking Patents: Did Acorda Create a New Paradigm?" (2020) Landslide, Volume 12, Number 4, 42-45.

DeForest McDuff and Nathan Koterba, "Formal Fridays: 60+ Strategies for Standing Out & Getting Promoted," (2018) Amazon Publishing.

DeForest McDuff, Gary Pavela, and Donald McCabe, "Updated: Ten Principles of Academic Integrity for Faculty," (2017) Integrity Seminars Resource.

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DeForest McDuff, Susan McDuff, Jennifer Farace, Carolyn Kelley, Maria Sovoia, and Jess Mandel, "Evaluating a Grading Change at UCSD School of Medicine: Pass/Fail Grading is Associated with Decreased Performance on Preclinical Exams but Unchanged Performance on USMLE Step 1 Scores" (2014) BioMed Central Medical Education 14:127.

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DeForest McDuff, "Quality, Tuition, and Applications to In-State Public Colleges," (2007) Economics of Education Review 26(4), 433–449.

DeForest McDuff, "Analyzing Income and Happiness: The Effects of Placing Too Much Emphasis on Income in a Job" (2005), Princeton manuscript.

Awards

IAM Patent 1000: Economic Experts. Awarded to top economic experts nationwide (approximately 100 experts) with expertise in economic patent analysis, 2020-present.

Towbes Teaching Prize for Outstanding Teaching. Awarded to top 4 teaching assistants in the economics department, Princeton University, 2006.

National Science Foundation Graduate Research Fellowship. Awarded to 25 graduate students in economics nationwide each year, Princeton University, 2005-2008.

Princeton University Graduate Research Fellowship. Full tuition fellowship and stipend for graduate research, Princeton University, 2004-2009.

Dillard Prize. Awarded to top undergraduate in economics, University of Maryland at College Park, 2004.

Presentations

"Physician Finances: from Resident to Attending," Harvard Residency Morning Conference, Boston MA, 2019; Duke University Residency Morning Conference, Durham NC, 2020-present.

"Price Optimization in E-Commerce," Presenter, Global Big Data Conference, Boston MA, 2016.

"Damages Whirlwind: Navigating Reasonable Royalties in 2015," Presenter, Boston Patent Law Association, Boston MA, 2015.

"Asset Valuation and Patent Monetization: A Review of Valuation Methods and Transaction Structures," Presenter, Law Seminars International, San Francisco CA, 2015.

"Jury Trials for At-Risk Generic Launches," Presenter, Continuing Legal Education, Los Angeles CA, 2015.

"Careers for PhDs in Start-ups," Panelist, University of California at San Diego, San Diego CA, 2014.

"How to Prove Reasonable Royalty in Patent Damages," Panelist, The Knowledge Congress, San Diego CA, 2013.

"Careers in Economics and Finance," Presenter, University of California at San Diego, San Diego CA, 2010.

"Home Price Risk, Local Market Shocks, and Index Hedging," Presenter, National Bureau of Economic Research, Boston MA, 2008.

Expert Testimony (Last 4 Years)

1. Amperex Technology Limited v. Semiconductor Energy Laboratory Co, Ltd. (E.D.V.A., 1:23-cv-00272). Evaluation of patent infringement including reasonable royalty damages related to battery products. Expert report.
2. Confidential Arbitration, CPR Arbitration. Evaluation of damages for legal malpractice and breach of fiduciary duty. Expert report, deposition.
3. DynaPass IP Holdings LLC v. BOKF, National Association (E.D. Tex., 2:22-cv-00211). Evaluation of reasonable royalty related to multi-factor authentication technology. Expert report.
4. Novo Nordisk Inc. and Novo Nordisk A/S v. Mylan Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.; Rio Biopharmaceuticals, Inc.; Zydus Lifesciences Limited f/k/a Cadila Healthcare Limited; Zydus Pharmaceuticals (USA) Inc.; Zydus Worldwide DMCC; Alvogen, Inc.; Sun Pharmaceutical Industries, Inc.; Sun Pharmaceutical Industries Limited (D. Del., 22-MD-3038-CFC). Evaluation of commercial success related to Ozempic (semaglutide). Expert report.

5. In the Inter Partes Review of U.S. Patent 10,335,462 (Mylan Pharmaceuticals, Inc., et al. v. Novo Nordisk A/S). (USPTO PTAB, IPR2023-00724). Evaluation of commercial success related to Ozempic (semaglutide). Expert declaration, deposition.
6. Alcon Inc., Alcon Vision, LLC, and Alcon Laboratories, Inc. v. Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (D. Del, 22-1422-WCB). Evaluation of commercial success related to Simbrinza (brinzolamide, brimonidine tartrate) for glaucoma and ocular hypertension. Expert report, deposition.
7. Cipla USA, Inc. v. Ipsen Biopharmaceuticals, Inc. (D. Del, 22-cv-00552-GBW-SRF). Evaluation of false advertising, unfair business competition, and violation of the Lanham Act related to pharmaceutical marketing. Expert report (x3), deposition.
8. Jonathan Berall, M.D., M.P.H. v. Teleflex Medical Incorporated (E.D.N.C., 5:22-cv-331-FL). Evaluation of reasonable royalty related to video laryngoscopes. Expert report (x2), deposition.
9. Exeltis USA, Inc., Laboratorios Leon Farma, S.A., Chemo Iberica, S.A., and Chemo Research, S.L. v. Lupin Ltd. and Lupin Pharmaceuticals, Inc. (D. Del., 22-cv-00434-RGA-MPT). Evaluation of commercial success related to Slynd (drospirenone) for contraception. Expert report, deposition, trial testimony.
10. Endo Par Innovation Company, LLC, Par Pharmaceutical, Inc., and Par Sterile Products, LLC v. Baxter Healthcare Corporation (D. Del., 23-cv-00538-GWB-SRF). Evaluation of irreparable harm, balance of hardships, public interest, and bond analysis related to Vasostrict (vasopressin) for the blood pressure regulation and kidney function. Expert declaration.
11. Exelixis Inc. v. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (D. Del., 22-cv-00228-RGA-JLH). Evaluation of commercial success related to Cabometyx and Cometriq (cabozantinib) for the treatment of kidney, liver, and thyroid cancers. Expert report, deposition, trial testimony.
12. Sandoz Inc. v. Amgen Inc. (C.D. Cal., 22-cv-05326-RGK-MAR). Evaluation of false advertising and unfair business competition related to pharmaceutical marketing. Expert report, deposition.
13. Broadcom Corporation and Avago Technologies International Sales PTE. Limited v. Netflix, Inc. (N.D. Cal., 20-cv-04677-JD). Evaluation of reasonable royalty related to video streaming. Expert report, deposition.
14. TwinStrand Biosciences, Inc., University of Washington v. Guardant Health, Inc. (D. Del., 21-1226-GBW-SRF). Evaluation of reasonable royalty related to cancer diagnostic tests. Expert report (x3), expert declaration, deposition, trial testimony.
15. Finjan, Inc. v. ESET, LLC; ESET SPOL. S.R.O (S.D. Cal., 3:17-cv-0183-CAB-BGS). Evaluation of reasonable royalty related to cybersecurity software. Expert report.
16. Vanda Pharmaceuticals Inc. v. Food and Drug Administration, et al. (D.D.C., 23-cv-280-TSC). Evaluation of irreparable harm, balance of hardships, public interest, and bond analysis related to Hetlioz (tasimelteon) for the treatment of Non-24 sleep disorders. Expert declaration.
17. Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc., Apotex Inc., Apotex Corp. (Fed. Cir., Case No. 2023-1247). Evaluation of irreparable harm, balance of hardships, public interest, and bond analysis related to Hetlioz (tasimelteon) for the treatment of Non-24 sleep disorders. Expert declaration.

18. University of Tennessee Research Foundation v. Caelum Biosciences, Inc.; The Trustees of Columbia University in the City of New York (E.D. Tenn., 3:19-cv-00508). Evaluation of breach of contract, trade secret misappropriation, and other claims related to antibody treatments for AL amyloidosis. Expert report (x2), deposition.

19. Medtronic, Inc.; Medtronic Puerto Rico Operations Co.; Medtronic Logistics, LLC; Medtronic USA, Inc. v. Axonics, Inc. f/k/a Axonics Modulation Technologies, Inc. (C.D. Cal., 8:19-cv-02115-DOC-JDE). Evaluation of patent damages, including lost profits and reasonable royalty, related to implantable sacral neuromodulation medical devices. Expert report (x3), deposition.

20. Pinkerton Tobacco Co., LP, Swedish Match North America LLC, and NYZ AB v. Kretek International, Inc. and Dryft Sciences, LLC (C.D. Cal., 2:20-cv-08729-SB-MRWx). Evaluation of damages for trade secret misappropriation related to nicotine pouch products. Expert report, deposition.

21. Confidential Arbitration, China. Valuation analysis of intellectual property in the automobile industry. Expert report.

22. Semiconductor Energy Laboratory Co., Ltd. v. TCL China Star Optoelectronics Technology Co., Ltd.; TCL Technology Group Corporation; TTE Technology, Inc.; TCL Communication Technology Holdings Limited; TCT Mobile, Inc.; and TCT Mobile (US) Inc. (C.D. Cal., 8:21-cv-00554-JAK-KES). Evaluation of reasonable royalty related to semiconductor devices. Expert report (x2), deposition.

23. In re Sugammadex (Merck Sharp & Dohme BV, Merck Sharp & Dohme Corp., Organon USA Inc. v. Aspiro Pharma Limited; Aurobindo Pharma Limited; Aurobindo Pharma USA, Inc.; Biophore India Pharmaceuticals Private Ltd.; Biophore Pharma Inc.; Dr. Reddy's Laboratories, Inc.; Dr. Reddy's Laboratories, Ltd.; Eugia Pharma Specialties Limited; Fisiopharma SRL; Fresenius Kabi USA, LLC; Gland Pharma Limited; Lek Pharmaceuticals dd; Lifestar Pharma LLC; Lupin Inc.; Lupin Limited; Lupin Pharmaceuticals, Inc.; Mankind Pharma Ltd.; MSN Laboratories Private Limited; MSN Life Sciences Private Ltd.; MSN Pharmaceuticals Inc.; Mylan API US LLC; Mylan Inc.; Mylan Pharmaceuticals Inc.; Sandoz, Inc.; Sun Pharmaceutical Industries Inc.; Sun Pharmaceutical Industries Limited; Teva Pharmaceuticals USA, Inc.; USV Private Limited; Zenara Pharma Ltd.; Zenara Pharma Private Limited; Zydus Lifesciences Limited f/k/a Cadila Healthcare Limited; Zydus Pharmaceuticals (USA) Inc.), (D.N.J., Case No. 2:20-cv-02576). Evaluation of commercial success related to Bridion (sugammadex) for the reversal of neuromuscular blockage. Expert report, deposition.

24. The United States of America v. Gilead Sciences, Inc. and Gilead Sciences Ireland UC (D. Del. 1:19-CV-02103-MN). Evaluation of reasonable royalty related to Truvada and Descovy (tenofovir and emtricitabine) for HIV pre-exposure prophylaxis. Expert report (x2), deposition, trial testimony.

25. Confidential Arbitration, American Arbitration Association. Evaluation of irreparable harm, balance of hardships, and public interest for the violation of restrictive covenants. Expert analysis, deposition, arbitration testimony.

26. Vifor Fresenius Medical Care Renal Pharma Ltd. and Vifor Fresenius Medical Care Renal Pharma France S.A.S. v. Teva Pharmaceuticals USA, Inc., (D. Del., 1:20-cv-00911-MN). Evaluation of commercial success related to Velphoro (sucroferric oxyhydroxide) for the treatment of chronic kidney disease and hyperphosphatemia. Expert report, deposition.

27. Exelixis Inc. v. MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (D. Del., 19-2017-RGA-SRF). Evaluation of commercial success related to Cabometyx and Cometriq

(cabozantinib) for the treatment of kidney, liver, and thyroid cancers. Expert report, deposition, trial testimony.

28. CA, Inc. and Avago Technologies International Sales Pte. Limited v. Netflix, Inc. (E.D. Tex., N.D. Cal., 2:21-cv-00080-JRG-RSP). Evaluation of reasonable royalty related to video streaming. Expert report, deposition.

29. FinancialApps, LLC v. Envestnet, Inc. and Yodlee, Inc. (D. Del., 1:19-cv-01337-CFC-CJB). Evaluation of damages for trade secrets misappropriation, fraud, tortious interference, unfair competition, deceptive trade practices, breach of contract, breach of implied covenant of good faith and fair dealing, and unjust enrichment related to financial software solutions. Expert report (x3), deposition.

30. Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV v. Pharmascience Inc., Mallinckrodt plc, and SpecGx LLC (D.N.J., 2:19-cv-21590). Evaluation of commercial success related to Invega Sustenna (paliperidone palmitate) for the treatment of schizophrenia and schizoaffective disorder. Expert report.

31. Confidential Arbitration, Switzerland. Evaluation of economic harm for breach of contract and trade secret misappropriation. Expert analysis, written testimony.

32. Gentex Corporation v. Galvion Ltd., Galvion Inc. (D. Del., 19-00921-MN). Evaluation of patent damages including reasonable royalty, lost profits, unjust enrichment, and contract royalties for military helmet equipment. Expert report, deposition.

33. Salix Pharmaceuticals, Ltd.; Salix Pharmaceuticals, Inc.; Bausch Health Ireland Ltd.; and Alfasigma S.P.A. v. Norwich Pharmaceuticals, Inc. (D. Del., 20-00430-RGA). Evaluation of commercial success related to Xifaxan (rifaximin) for the treatment of hepatic encephalopathy and irritable bowel syndrome with diarrhea. Expert report, deposition.

34. Volterra Semiconductor LLC v. Monolithic Power Systems, Inc. (D. Del., 1:19-cv-02240). Evaluation of patent infringement, economic damages, and reasonable royalty related to integrated chip power solutions. Expert report (x2), deposition.

35. Horizon Medicines LLC v. Alkem Laboratories Ltd. (D. Del., 1:18-cv-01014). Evaluation of irreparable harm, balance of hardships, and public interest with respect to patent infringement and the commercial performance of Duexis (ibuprofen famotidine). Expert declaration.

36. Rubicon Research Private Limited v. Kartha Pharmaceuticals Inc., and Manoj Babu Mazhuvancheril; Zaklady Farmaceutyczne Polpharma S.A. v. Kartha Pharmaceuticals, Inc. (W.D.N.C., 3:21-cv-00129-MOC-DSK; 3:21-cv-00129-GCM). Evaluation of irreparable harm, public interest, balance of hardships, and bond related to trade secret misappropriation and breach of contract in pharmaceutical product development. Expert report.

37. Confidential Arbitration, California. Evaluation of breach of contract and business impact related to dentistry medical devices. Expert analysis, deposition, arbitration testimony.

38. Fresenius Kabi USA, LLC v. Custopharm, Inc. (W.D. Tex., 6:21-cv-00286-ADA). Evaluation of irreparable harm, balance of hardships, and public interest related to patent infringement and the treatment of myxedema coma and hypothyroidism. Expert declarations (x2).

39. Syngenta Crop Protection, LLC v. Atticus, LLC (W.D.N.C., 5-19-cv-00509). Evaluation of patent infringement, economic damages, reasonable royalty, and commercial success related to agricultural chemicals. Expert reports (x2), deposition.

40. Rebecca Holland New v. Thermo Fisher Scientific, Inc. (M.D.N.C, 1:19-cv-00807-TDS-LPA). Evaluation of economic damages due to alleged discrimination, harassment, hostile and abusive working environment, retaliation, breach of contract, conversion, fraud, and failure to pay wages and benefits. Expert reports (x3).

41. Brian C. Williams, et al. v. The Estates LLC, et al. (M.D.N.C, 1:19-cv-00176-CCE-JLW). Evaluation of class certification and antitrust claims related to bid rigging and real estate foreclosures. Expert report.

42. In the Matter of Certain Non-Invasive Aesthetic Body-Contouring Devices, Components Thereof, and Methods of Using Same (BTL Industries, Inc., et al. v. Allergan, Inc. et al.) (ITC, 337-TA-1219). Evaluation of domestic industry, commercial success, bond, and remedy related to body contour products. Expert report, deposition, trial testimony.

43. Confidential Arbitration, American Arbitration Association. Evaluation of business valuation for software as a service companies and consumer facing web-based retail companies. Expert report.

44. Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation v. MSN Laboratories Private Ltd., MSN Pharmaceuticals, Inc., Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., Lupin Limited, Lupin Pharmaceuticals Inc., Dr. Reddy's Laboratories Ltd., Dr. Reddy's Laboratories, Inc., Cipla Limited, Cipla USA, and InvaGen Pharmaceuticals, Inc., Mankind Pharma Ltd., Lifestar Pharma LLC, Alkem Laboratories Ltd., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Laurus Labs Ltd., Laurus Generics Inc., Alembic Pharmaceuticals Ltd., Alembic Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Limited, Aizant Drug Research Solutions Pvt. Ltd., Prinston Pharmaceutical Inc. (D. Del., 18-cv-01689-CFC). Evaluation of commercial success related to Jardiance, Glyxami, Synjardy, and Synjardy XR (empagliflozin) for the treatment of Type 2 diabetes. Expert report, deposition.

45. Wash World, Inc. v. Belanger, Inc. and Piston OPW, Inc. d/b/a OPW Inc. (E.D. Wis., EDWI-1-19-cv-01562). Evaluation of lost profits and reasonable royalty related to mechanical car wash systems. Expert report, deposition, trial testimony.

46. Arbor Global Strategies, LLC v. Samsung Electronics Co., Ltd., Samsung Electronics America, Inc., and Samsung Semiconductor, Inc. (E.D. Tex., EDTX-2-19-cv-00333). Evaluation of reasonable royalty related to semiconductors, integrated circuits, and electronics hardware. Expert report, deposition.

47. Finjan, LLC v. Qualys, Inc. (N.D. Cal., 4:18-cv-07229-YGT). Evaluation of reasonable royalty related to cybersecurity software. Expert report, deposition.

48. In the Inter Partes Review of U.S. Patent Nos. 8,257,723 and 7,744,913 (Palette Life Sciences, Inc. v. Incept LLC) (USPTO PTAB, IPR2020-00002, IPR2020-00004). Evaluation of commercial success related to spacer technology for prostate cancer treatment. Expert declaration, deposition.

49. SmileDirectClub, LLC v. Candid Care Co. (D. Del., 20-cv-00583-CFC). Evaluation of irreparable harm, balance of hardships, and public interest related to dental alignment. Expert declaration.

50. Finjan, LLC v. SonicWall, Inc. (N.D. Cal., 5:17-cv-04467-BLF). Evaluation of reasonable royalty related to cybersecurity software. Expert report, deposition.

51. Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc., Apotex Inc., Apotex Corp., MSN Pharmaceuticals Inc., MSN Laboratories Private Limited (D. Del., 1:18-cv-00651, 1:18-cv-00689,

and 1:18-cv-000690). Evaluation of commercial success related to Hetlioz (tasimelteon) for the treatment of Non-24 sleep disorders. Expert reports (x2), deposition.

52. Pharmacyclics LLC and Janssen Biotech, Inc. v. Zydus Worldwide DMCC, et al., Pharmacyclics LLC and Janssen Biotech, Inc. v. Alvogen Pine Books LLC and Natco Pharma LTD (D. Del., 1-18-cv-00192-CFC, 1-19-cv-00434-CFC-CJB). Evaluation of commercial success related to Imbruvica (ibrutinib) to treat non-Hodgkin's lymphoma. Expert report, deposition, trial testimony.

53. In the Inter Partes Review of U.S. Patent Nos. 8,993,300, 8,455,232, 7,312,063, 7,829,318, 6,451,572, and 7,026,150 (Associated British Foods PLC, AB Vista, Inc., PGP International Inc., Abitec Corporation, AB Enzymes, Inc., and AB Enzymes GMBH v. Cornell Research Foundation, Inc.) (USPTO PTAB, IPR2019-00577, IPR2019-00578, IPR2019-00579, IPR2019-00580, IPR2019-00581, IPR2019-00582). Evaluation of commercial success related to OptiPhos and Quantum products related to animal feed enzymes. Expert declaration.

54. Sonrai Systems, LLC v. Anthony M. Romano, Geotab, Inc., The Heil Co. d/b/a Environmental Solutions Group, and Alliance Wireless Technologies, Inc. (N.D. Ill., 16-cv-03371). Evaluation of trade secret misappropriation, interference with contracts, unfair competition, breach of contract, and other issues related to automobile telematics. Expert report, deposition.

55. Wirtgen America, Inc. v. United States of America, Department of Homeland Security, U.S. Customs and Border Protection, et al. (D.D.C., 20-cv-00195-CRC). Evaluation of competition and irreparable harm related to the importation of road milling machines. Expert declaration, hearing testimony.

56. In the Inter Partes Review of U.S. Patent 8,679,069 (Pfizer Inc. v. Sanofi-Aventis Deutschland GMBH) (USPTO PTAB, IPR2018-00979). Evaluation of commercial success related to Lantus SoloStar (insulin glargine) for the treatment of diabetes. Expert declaration.

57. Vifor Fresenius Medical Care Renal Pharma Ltd., Vifor Fresenius Medical Care Renal Pharma France S.A.S. v. Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc. (D. Del., 1:18-cv-00390-MN). Evaluation of commercial success related to Velphoro (sucroferric oxyhydroxide) for the treatment of chronic kidney disease and hyperphosphatemia. Expert report, deposition, trial testimony.

58. Impax Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc. (D.N.J., 2:17-cv-13476). Evaluation of commercial success related to Rytary (carbidopa and levodopa) for the treatment of Parkinson's disease. Expert report, deposition.

59. Mitsubishi Tanabe Pharma Corporation, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag Gmbh International v. Sandoz Inc. and Zydus Pharmaceuticals (USA) Inc. (D.N.J., 17-05319, 17-06375, 17-12082, 18-06112). Evaluation of commercial success related to Invokana, Invokamet, and Invokamet XR (canagliflozin) for the treatment of Type 2 diabetes. Expert report, deposition, trial testimony.

60. Sanofi-Aventis US LLC, Sanofi-Aventis Deutschland GMBH, and Sanofi Winthrop Industrie, Biocon Limited, Biocon Research Ltd., Biocon S.A., Biocon Sdn. Bhd. v. Mylan GMBH, Mylan Inc., Mylan NV, And Mylan Pharmaceuticals Inc. (D.N.J., 17-cv-09105-SRC-CLW). Evaluation of commercial success related to Lantus Vial and Lantus SoloStar (insulin glargine) for the treatment of diabetes. Expert report, deposition, trial testimony.

Exhibit A-2
Materials Considered or Relied Upon

Pleadings and Filings

Opening Brief in support of Novartis's Motion for a Rule 62(d) Injunction Pending Appeal and Temporary Restraining Order Pending Resolution of this Motion, 8/2/2024.

Opening Brief in Support of Novartis's Motion for Preliminary Injunction Against MSN, 8/2/2024.

Declarations

Declaration of Bharat Reddy Chintapally, 8/6/2024.

Vellturo Declaration, 8/2/2024.

Patents

U.S. Patent No. 11,096,918 B2	Amorphous Solid Form of Compounds…, filed 9/23/2019, issued 8/24/2021.
U.S. Patent No. 8,101,659 B2	Methods of Treatment and Pharmaceutical Composition, filed 6/27/2008, issued 1/24/2012.

Research Materials

FDA (2019), "Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices."

Novartis Annual Reports: 2016-2023.

Regan, Tracy L. (2008), "Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market," International Journal of Industrial Organization 26:930–948.

Yu, Gupta (2014), "Pioneering advantage in generic drug competition," International Journal of Pharmaceutical and Healthcare Marketing, Vol. 8 No. 2, 2014.

Exhibit B-1
Entresto Annual Sales

Description	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024 (Extended)	Total
Entresto U.S Net Sales	$ 11	$ 87	$ 297	$ 556	$ 925	$ 1,277	$ 1,712	$ 2,354	$ 3,067	$ [redacted]	$ [redacted]
YoY Growth (%)	*n/a*	*710%*	*243%*	*87%*	*66%*	*38%*	*34%*	*38%*	*30%*	[redacted]	[redacted]
Entresto Rest of World Net Sales	$ 10	$ 83	$ 210	$ 472	$ 801	$ 1,220	$ 1,836	$ 2,290	$ 2,968	$ [redacted]	$ [redacted]
YoY Growth (%)	*n/a*	*710%*	*152%*	*125%*	*70%*	*52%*	*50%*	*25%*	*30%*	[redacted]	[redacted]
Entresto Total Net Sales	**$ 21**	**$ 170**	**$ 507**	**$ 1,028**	**$ 1,726**	**$ 2,497**	**$ 3,548**	**$ 4,644**	**$ 6,035**	**$** [redacted]	**$** [redacted]

Notes and sources:
All figures in millions of USD.
2015-2016: Novartis 2016 Annual Report, at 198.
U.S. and Rest of World Net Sales estimated in these years based on ratio of U.S. and Rest of World sales from 2017 through 2023 and total Entresto Net sales for 2015 and 2016.
2017-2018: Novartis 2018 Annual Report, at 83 and 93.
2019-2020: Novartis 2020 Annual Report, at F-25 and F-26.
2021-2022: Novartis 2022 Annual Report, at F-23 and F-24.
2023: Novartis 2023 Annual Report, at F-19.
2024: Vellturo Declaration, 8/2/2024, Exhibit 13.
Rest of World and Total Net Sales are estimated based on U.S. sales growth from 2023 to 2024 in Vellturo Declaration.
Actual U.S. net sales of Entresto in H1 2024 were $1,895.

Exhibit B-2
Novartis Income Statements

Description	2019	2020	2021	2022	2023
Net Revenue	$ 47,498	$ 48,659	$ 51,626	$ 42,206	$ 45,440
Other Revenues	$ 1,179	$ 1,239	$ 1,251	$ 1,255	$ 1,220
Cost of Goods Sold	$ (14,425)	$ (15,121)	$ (15,867)	$ (11,582)	$ (12,472)
Gross Profit	$ 34,252	$ 34,777	$ 37,010	$ 31,879	$ 34,188
Gross Margin (%)	72.1%	71.5%	71.7%	75.5%	75.2%
Selling, General and Administration	$ (14,369)	$ (14,197)	$ (14,886)	$ (12,193)	$ (12,517)
Research and Development	$ (9,402)	$ (8,980)	$ (9,540)	$ (9,172)	$ (11,371)
Other Operating Income (Expense)	$ (1,395)	$ (1,448)	$ (895)	$ (2,568)	$ (531)
Total Operating Expenses	$ (25,166)	$ (24,625)	$ (25,321)	$ (23,933)	$ (24,419)
Operating Profit	$ 9,086	$ 10,152	$ 11,689	$ 7,946	$ 9,769
Operating Margin (%)	19.1%	20.9%	22.6%	18.8%	21.5%
Income Before Taxes from Continuing Operations	$ 8,940	$ 9,878	$ 26,137	$ 7,177	$ 9,123
Net Income From Continuing Operations	$ 7,147	$ 8,071	$ 24,018	$ 6,049	$ 8,572
Net Income from Discontinued Operations	$ 4,590	$ -	$ -	$ 906	$ 6,282
Net Income	$ 11,737	$ 8,071	$ 24,018	$ 6,955	$ 14,854

Notes and sources:
All monetary figures are in millions of USD.
2019: Novartis 2019 Annual Report, at F-1.
$53 billion in "Sales to discontinued segment" included as Net Revenue.
2020-2021: Novartis 2021 Annual Report, at 54.
2022-2023: Novartis 2023 Annual Report, at 43.

Exhibit B-3
Novartis Balance Sheets

Description	2019	2020	2021	2022	2023
Cash and Cash Equivalents	$ 11,112	$ 9,658	$ 12,407	$ 7,517	$ 13,393
Total Current Assets	$ 28,663	$ 29,673	$ 45,718	$ 36,910	$ 30,481
Total Non-current Assets	$ 88,866	$ 98,105	$ 86,077	$ 80,543	$ 69,464
Total Assets	**$ 118,370**	**$ 127,778**	**$ 131,795**	**$ 117,453**	**$ 99,945**
Total Current Liabilities	$ 28,233	$ 33,059	$ 30,208	$ 28,656	$ 26,390
Total Non-current Liabilities	$ 34,555	$ 38,053	$ 33,765	$ 29,374	$ 26,805
Total Liabilities	$ 62,788	$ 71,112	$ 63,973	$ 58,030	$ 53,195
Total Equity	$ 55,551	$ 56,666	$ 67,822	$ 59,423	$ 46,750
Total Equity and Liabilities	**$ 118,370**	**$ 127,778**	**$ 131,795**	**$ 117,453**	**$ 99,945**

Notes and sources:
All monetary figures are in millions of USD.
2019: Novartis 2019 Annual Report, at F-3.
2019 assets include $841 million relating to disposal group held for sale and 2019 liabilities include $31 million relating to disposal group held for sale.
2020-2021: Novartis 2021 Annual Report, at 77.
2022-2023: Novartis 2023 Annual Report, at 79.

CERTIFICATE OF SERVICE

I hereby certify that on August 6, 2024, I caused a copy of the foregoing document(s) to be served by e-mail to the following counsel listed below.

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